

PACKAGE LEAFLET: INFORMATION LEAFLET FOR THE USER**Bisacodyl 5mg Gastro-resistant Tablets
(Bisacodyl)**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days of treatment.

What is in this leaflet

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1. WHAT BISACODYL IS AND WHAT IT IS USED FOR

- Bisacodyl 5mg Gastro-resistant tablets contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives.
- Bisacodyl is used for the short-term relief from occasional constipation.
- Bisacodyl can also be used in a hospital to empty a person's bowel before child birth, surgery or radiological investigations.
- Bisacodyl gently stimulate the muscles of the bowel (large intestine). This brings predictable, overnight relief from constipation.
- Bisacodyl 5mg Gastro-resistant Tablets have a special coating that helps to ensure the medicine works only where it is needed.
- Bisacodyl 5mg Gastro-resistant Tablets do not help with weight loss.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is 'normal and regular' varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people. For others, it may happen more often.
- It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Loss of 'tone' in the bowel muscles in older people
- Pregnancy

- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally 'off colour'. Sometimes it causes headaches.

These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables.
- Drink enough water so that you do not become dehydrated.
- Keep up your exercise and stay fit.
- Make time to empty your bowel when your body tells you.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BISACODYL

Do not take Bisacodyl if:

- You are allergic to bisacodyl or any of the other ingredients in this medicine. (listed in Section 6).
- You are intolerant to or cannot digest some sugars (as the tablet contains a small amount of lactose and sucrose).
- You have severe dehydration.
- You have a bowel condition called 'ileus' (blockage in the intestine).
- You have a serious abdominal condition such as appendicitis.
- You have severe abdominal pain with nausea and vomiting.
- You have a blocked bowel (intestinal obstruction).
- You have inflammation of the bowel (small or large intestine).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bisacodyl

Other medicines and Bisacodyl

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Bisacodyl can affect the way some other medicines work. Also, some other medicines can affect the way Bisacodyl works.

In particular, tell your doctor or pharmacist if you are taking:

- water tablets (diuretics) such as bendrofluazide or furosemide (frusemide)
- steroid medicines such as prednisolone
- Other laxative medicines

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Bisacodyl 5mg Gastro-resistant Tablets.

Pregnancy and breast feeding

Talk to your doctor or pharmacist before taking Bisacodyl if you are pregnant, planning to become pregnant or are breast feeding.

Driving and using machines

Some people may feel dizzy or faint while taking this medicine. If this happens to you, wait until these feelings go away before driving or using machines.

Bisacodyl contains Lactose, Sucrose and Tartrazine

This medicine contains lactose (a milk sugar) and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. The tablets also contain Tartrazine (E102) which may cause allergic reactions.

3. HOW TO TAKE BISACODYL

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

As with all laxatives, Bisacodyl should not be taken every day for more than five days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

Taking this medicine:

- Swallow the tablets whole with water.
- Milk, antacids or proton pump inhibitors (medicines which reduce stomach acid) should not be taken within one hour before or after taking Bisacodyl. This is because they will stop Bisacodyl from working properly.

How much to take***Adults and children over 10 years old***

- Take one or two tablets (5 to 10 mg) daily before bedtime.
- If you have not taken Bisacodyl 5mg Gastro-resistant Tablets before, start with one tablet and increase to two if necessary.
- When your bowel regularity has returned to normal, the dose can usually be stopped.

Children aged between 4 and 10 years

Bisacodyl 5mg Gastro-resistant Tablets should only be given to children between the ages of 4 and 10 if recommended by a doctor. The usual dose for children is:

- one tablet (5 mg) daily before bedtime.

Children under 4 years

Bisacodyl 5mg Gastro-resistant Tablets are not recommended for children under 4 years.

If you take more Bisacodyl than you should

It may be harmful to:

- take too much bisacodyl
- take bisacodyl for too long

This is because taking too much for too long may lead to:

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- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.

- Low levels of potassium in the blood (called 'hypo-kalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you; this is so the doctor knows what you have taken.

If you forget to take Bisacodyl

If you have forgotten to take your tablet at night, wait for the next dose and continue as before. Do not take any more tablets in one day than your doctor has prescribed. Do not take a double dose to make up for a missed dose.

If you feel that the effect of your medicine is too strong or too weak, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bisacodyl can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Rare side effects (affect less than 1 in 1000 people)

- Severe allergic reactions which may cause swelling of the face or throat and difficulty in breathing or dizziness.
If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away.
- Colitis (inflammation of the large intestine which causes abdominal pain and diarrhea)
- Dehydration
- Allergic reactions which may cause a skin rash
- Fainting

Uncommon side effects (affect less than 1 in 100 people)

- Blood in the stools
- Vomiting
- Abdominal discomfort
- Discomfort inside and around the back passage
- Dizziness

Common side effects (affect less than 1 in 10 people):

- Abdominal cramps or pain
- Diarrhoea
- Nausea

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BISACODYL

Keep this medicine out of the sight and reach of children.

Do not use Bisacodyl after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container.

Keep the container tightly closed (for polypropylene containers only).

Do not use Bisacodyl if you notice any deterioration or damage to the outer packaging

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bisacodyl contains

- The active substance is Bisacodyl. Each tablet contains 5 mg of bisacodyl.
- The other ingredients are: Core Tablet: Lactose monohydrate, Liquid paraffin, Maize starch and Magnesium stearate. Enteric Coating: Methacrylic acid Co-Polymer Ethyl Acrylate Co Polymer (1:1) dispersion 30% material, Macrogol 3350, Talc and Simethicone PD30. Sugar Coat: Povidone K30, Talc, Kaolin light and Sucrose. Colour Coat: Titanium dioxide (E171) and Tartrazine lake (E102). Polishing: Carnauba wax.

What Bisacodyl looks like and contents of the pack

Bisacodyl are yellow shiny biconvex sugar coated gastro resistant tablets.

Bisacodyl 5mg, gastro-resistant tablets are available in blister packs (cartons) of 20, 60 and 100 tablets and in polypropylene containers of 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Chanelle Medical, Loughrea, Co. Galway, Ireland.

Manufacturer

Chanelle Medical, Loughrea, Co. Galway, Ireland.

The distributor is Healthcare Pharma Limited, 3, Young Place, Kelvin Industrial Estate, East Kilbride, Glasgow, G75 0TD, United Kingdom.

This leaflet was last revised in: March 2019.